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Supreme Court of the United States

October Term, 1992

WILLIAM DAUBERT and JOYCE DAUBERT, INDIVIDUALLY AND AS GUARDIANS AD LITEM FOR JASON DAUBERT, AND ANITA DE YOUNG, INDIVIDUALLY AND AS GUARDIAN AD LITEM FOR ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

REPLY BRIEF OF PETITIONERS

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REPLY BRIEF OF PETITIONERS

Some of the central points in our opening brief have been conceded and/or confirmed by the briefs of Merrell and *amici curiae*:

1. A wide spectrum of *amici curiae* agrees that the "general acceptance" (or *Frye)* test applied by the Ninth Circuit in this case is not a proper interpretation of the Federal Rules of Evidence ("FRE"). *See, e.g.*, the briefs of the United States ("U.S. Br.") 17-18, the Group of American Law Professors ("Law Profs. Br.") 5-7, the Carnegie Commission 7-9, the American College of Legal Medicine 7-8, and the American Medical Association ("AMA Br.") 9. Even Merrell, while paying brief lip service to the *Frye* test (Resp. Br. 25-26), proffers as the *correct* interpretation of the FRE a test that differs from the one applied by the courts below (*id.* 12-24, 27-35). In short, the rationale on which the Ninth Circuit relied is defended by nothing more than a fig leaf, and the answer to the first question presented is — almost by default — "no."

2. Briefs filed by several scientific organizations confirm that the Ninth Circuit also erred in holding that scientists generally do not accept and rely upon reanalyses of epidemiological data unless they have been published and peer reviewed.[1]

3. No one has challenged petitioners' contention that California courts would admit the testimony of petitioners' experts and find it sufficient (as the District of Columbia Court of Appeals found it sufficient, *see* Pet. Br. 42) to support a jury

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[1] *See* Brief of Physicians, Scientists and Historians ("Physicians Br.) 4, 16-19; Brief of American Society of Law, Medicine & Ethics ("ASLME Br.") 10, 17-20; Brief of Kenneth Rothman *et al.* 12-13; Carnegie Commission Br. 25-28. *See also* Brief of Alvin R. Feinstein 8-10. The unreliability of publication and peer review as criteria for assuring scientific rigor, and the relative advantages of cross-examination for that purpose, are described in Brief of Daryl Chubin *et al.* 12, 18-24, 28-30. See also other concessions in the briefs of *amici* supporting Merrell: Brief of American Association for the Advancement of Science *et al.* 16, 21; AMA Br. 17; Brief of Nicolaas Bloembergen *et al.* 8-10; Brief of New England Journal of Medicine 3, 5, 11, 15.

finding of causation. The description of each State's rules in the brief of Texas *et al.* ("States' Br.") 5-9, suggests that the testimony would be admissible in at least 45 and possibly all 50 States. This highlights the federalism issue posed when the FRE are applied, as they were by the courts below, to distort the outcomes of state tort suits by excluding evidence the State deems sufficient to trigger its compensatory tort mechanisms.

We respond below to the matters which *are* contended in the briefs of Merrell and its supporting *amici*.

I. MISCHARACTERIZATIONS OF THE RECORD BY MERRELL AND ITS *AMICI*

This case does not involve "junk science." The experts whose testimony was proffered by petitioners are highly credentialed scientists, some of whom hold important governmental posts; their principal occupation consists of making probabilistic determinations of whether particular substances cause injuries observed in the population. For several decades Adrian Gross has been a high-level official of both the FDA and the EPA, responsible for making probabilistic determinations of causation upon which those agencies rely. Jay Glasser is the *court-appointed* epidemiological expert on causation in the Dalkon Shield litigation. Shanna Swan is the chief epidemiologist for a major department of the State of California. Stewart Newman is one of the nation's leading experts on the formation of the human limb. Pet. Br. 3 n.5.

These experts did not arrive at their opinions by reading tea leaves[2] or by instructing a computer to randomize the raw numbers in Bendectin studies done by others.[3] Rather, as their testimony explains in elaborate detail,[4] they applied well-established methodologies that scientists customarily employ — indeed, that they themselves employ in their daily scientific work

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[2] A hypothetical discussed in Law Profs. Br. 14.

[3] A hypothetical discussed in Resp. Br. 35.

[4] For each of these witnesses, the record contains hundreds of pages of testimony detailing the methodology by which they reached their ultimate conclusions. See Tabs 12, 21, 26, 32, cited in Pet. Br. 3 n.4.

advising their governmental employers — to assess the likelihood that Bendectin causes human limb defects. Pet Br. 5. The methods employed by petitioners' experts[5] are precisely the methods routinely employed by scientists, indeed, prescribed by federal regulations, to assess the probability that a particular drug is causing observed injuries.[6]

No evidence was introduced below *disputing* that the methodologies of these scientists were those customarily employed by scientists investigating causation. The district court's opinion in this case recites that Swan's opinion is based on "the methodology . . . generally and reasonably relied upon by epidemiologists . . . in trying to draw opinions concerning whether or not there is a cause and effect relationship between a drug and a birth defect" (J.A. 233 (quoting Swan Aff. at 7-8)), and that Glasser's opinion rests on "techniques that are generally and reasonably relied upon by biometrists, epidemiologists, and biostatisticians." J.A. 234. The disagreement between petitioners' and Merrell's experts is not in their methodologies, but in the conclusions they have reached upon appraising evidence gathered through a common methodology.

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[5] The methodology these experts employed was to examine the results of *in vivo* studies documenting the effect of Bendectin on animals, to analyze the results of *in vitro* microscopic examinations of cells exposed to Bendectin, to analyze the chemistry of Bendectin in light of knowledge of the effect of similar chemicals upon human limb birth defects, to analyze the data collected in the various attempts to survey the effect of Bendectin on humans (*i.e.*, the epidemiological data), and from the entirety of this data to evaluate the likelihood that Bendectin causes human limb defects. Pet. Br. 4-6.

[6] The applicable regulations are described in ASLME Br. 10-20. A 1991 EPA Guideline declares that "[i]n almost all cases, experimental animal data are predictive of a developmental effect in humans." *Id.* 12. Ideally, evidence regarding the effect on humans would be the best data, but federal agencies have found that limitations in the ability to derive epidemiological data have made such data a relatively unreliable predictor for most substances. *Id.* 14-16. In consequence, the accepted scientific approach is to examine, evaluate and integrate all available animal, chemical and epidemiological data. *Id.* 11-13, 16-17. The absence of statistically significance indices of causation is *not* regarded as conclusive. *Id.* 14-16.

Merrell suggests that the epidemiological evidence "demonstrat[es]" the safety of Bendectin. Resp. Br. 43 n.33. This is not accurate. The correct formulation is the one in Merrell's initial description of the epidemiological evidence: "no published study has found any *statistically significant* association between Bendectin and the sort of birth defects (limb reduction) at issue here." Resp. Br. 4 (emphasis added). The *amicus* briefs of many scientists corroborate the testimony of petitioners' experts that epidemiological evidence not meeting *95 percent* statistical significance may still be probative of causation, and assuredly does not demonstrate the *absence* of causation.[7] Indeed, even the district court recognized that the epidemiological evidence here leaves it "possible" that there was causation (J.A. 236), though that court ruled the evidence insufficient to sustain plaintiffs' burden of going forward because it thought statistical significance was required as a matter of law. J.A. 235-36.

The authors of the most "dramatic" (Resp. Br. 4) epidemiological study relied upon by Merrell, after stating their conclusion that a meta-analysis of the epidemiological evidence did not show an association between Bendectin and human birth defects, acknowledged that this finding should be a "relatively minor" factor in the overall assessment of whether Bendectin causes birth defects.[8] These authors explained:

> Meta-analysis of Bendectin teratogenicity studies [i.e., epidemiological studies] . . . alone should not be the sole determinant of whether a particular compound can be used safely in pregnancy. Instead, such a decision should be based on all available information, including *in vitro* data, and animal teratogenicity testing, as well as a good measure of common sense, particularly when considering the

[7] Rothman Br. 3-8; ASLME Br. 14-16; Carnegie Commission Br. 22 n. 29; Physicians' Br. 12-13; Feinstein Br. 12-16.

[8] Einarson, *et al.*, *A Method for Meta-Analysis of Epidemiological Studies*, 22 Drug Intelligence and Clinical Pharmacy 813, 822 (1988). In any event, the method employed in this study has been criticized by one of Merrell's *amici* as a "highly controversial procedure" that goes well beyond mixing apples and oranges, and is more like mixing a "fruit salad" with a "garden salad, shrimp salad, and pasta salad." Feinstein Br. 10.

> temporal relationship between exposure to the agent in question and the outcome of interest.[9]

It is upon consideration of this totality of factors that petitioners' experts based their opinions that, likelier than not, Bendectin causes human limb defects. Pet. Br. 6-7.

II. THE INADEQUACY OF THE EFFORTS TO LOCATE *FRYE* OR SOME OTHER "RELIABILITY" THRESHOLD IN RULE 702

Merrell makes a feeble attempt to defend *Frye*, which we refute in Part II-A, *infra*. Merrell then tries, as do its supporting *amici*, to locate some less stringent "reliability" threshold in Rule 702. The latter, even if correct, would require a reversal of the decision below. But it is not correct. As we show in Parts II-B and II-C, *infra*, these arguments attempt to secure by judicial fiat what both the Civil Rules Advisory Committee and the Solicitor General recently acknowledged is *not* now in the FRE. In Part II-D, *infra*, we furnish the analytical demonstration, from the text and structure of the FRE, of the infirmities of the attempt to locate a reliability threshold in Rule 702.

A. The "General Acceptance" Standard of *Frye*

Although Merrell clings at least nominally to a defense of the proposition that the FRE incorporates the "general acceptance" standard of *Frye*, that standard is condemned by a wide cross-section of *amici* as both a misreading of the FRE and bad policy. See p. 1, *supra*. Recently, the Civil Rules Advisory Committee made clear that it, too, believes *Frye* was not adopted by the

[9] Einarson, *et al.*, *supra*, at 822. The authors further cautioned that their methodology might have "masked" evidence of Bendectin's causative properties. *Id.* The Sixth Circuit decision that Merrell cites for the consistency of courts in its favor (Resp. Br. 5), after reviewing Merrell's "near-library" of data (Resp. Br. 11), actually found that Merrell "overstates the power of these statistical studies," which are "by no means conclusive" and show "possible" causation. *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1357 (6th Cir. 1992), *cert. denied*, 113 S. Ct. 84 (1992). The Sixth Circuit also noted that Merrell had been refused summary judgment in eight cases. *Id.* at 1352.

FRE and should not be added. Although proposing that the threshold for admission of expert testimony be raised to require greater reliability, the Committee emphasized that its proposal "does not mandate a return to the strictures of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) (requiring general acceptance of the scientific premises on which the testimony is based)." *Proposed Rules*, 137 F.R.D. 53, 157 (1991).

Merrell's lone effort to salvage the *Frye* test rests entirely on the proposition that because Congress did not expressly say it was abandoning *Frye*, the test's survival should be inferred. Resp. Br. 25-26. But a legislative intention *not* to accept the *Frye* rule is manifest in the enactment of the FRE: (1) *Frye* was widely condemned by commentators at the time the FRE were adopted (Pet. Br. 17); (2) as has been recognized by this Court (Pet. Br. 29), the Solicitor General (p. 7-8, *infra*), and recently the Civil Rules Advisory Committee (p. 6-7, *infra*), the framers expressly avowed an intent to remove common law barriers to the admissibility of expert opinion testimony; and (3) the plain words of Rule 402, read in conjunction with Rules 701-06, articulate a different standard than *Frye* (Pet. Br. 18-28).[10]

B. The Civil Rules Advisory Committee's Proposal

Merrell and many of the opposing *amici* urge this Court to find in the *present* text of Rule 702 the limitation on admissibility that the Civil Rules Advisory Committee proposed to *create* by amending Rule 702. In recently proposing to add a requirement that expert testimony be limited to "reasonably reliable" information, *Proposed Rules*, 137 F.R.D. 53, 73, 156 (1991), the Committee understood that this limitation did not already

[10] In any event, *Frye* had never been embraced by this Court, and, as of 1975, had never been applied by a federal appellate court to a civil case; indeed, only on three occasions, the first in 1984, has *Frye* been invoked to exclude expert testimony in a civil case. States' Br. 1-2 & n.1, 4-5. *Frye* has always been understood to be premised at least in part on considerations unique to criminal cases: the higher burden of proof, and the policy concern that criminal defendants could not afford to hire experts to counter those presented by the prosecutor. See *id.* 2-4. This, then, is hardly a situation where there was settled law for civil cases that Congress could be thought by silence to have incorporated into the FRE.

exist in Rule 702.

The Committee recognized that the greatly increased use of expert testimony following enactment of the FRE "was intended by the drafters of the rule, who were responding to concerns that the restraints previously imposed on expert testimony were artificial and an impediment to the illumination of technical issues in dispute." *Id.* at 156. But, the Committee opined, times have changed since 1975: now "large expenditures for marginally useful expert testimony ha[ve] become commonplace," and "excesses . . . should be curtailed." *Id.* at 156-57. The Committee explained that its "revision" (requiring that expert testimony be "reasonably reliable") would "limit the use, but increase the utility and reliability" of "testimony bearing on scientific and technical issues." *Id.* at 156; *see also id.* at 157.

Even this proposal, designedly less preclusive than *Frye*, proved to be highly controversial.[11] The proposal was formally withdrawn, to be resubmitted to a newly appointed Advisory Committee on evidence. This Court should not find *already in Rule 702* what the Civil Rules Advisory Committee correctly understood required amendment to achieve.

C. The Solicitor General's Proposal

In a brief filed on January 19, 1993, the Acting Solicitor General asked this Court to interpret Rule 702 as already containing some of the "reforms" that President Bush's Council on Competitiveness previously declared could be accomplished

[11] *See, e.g.*, Jack B. Weinstein, *Rule 702 of the Federal Rules of Evidence is Sound; It Should Not Be Amended*, 138 F.R.D. 631, 636 (1991); Advisory Committee on the Civil Rules, *Summary of Comments on 1991 Proposed Amendments*, May 20, 1992, at 62-66. Indeed, the Criminal Rules Advisory Committee strongly opposed the Civil Rules Advisory Committee's proposed amendment of Rule 702, reflecting significant "tensions and confusion" in the area of expert testimony. Edward R. Becker & Aviva Orenstein, *The Federal Rules of Evidence After Sixteen Years — The Effect of "Plain Meaning" Jurisprudence, the Need for an Advisory Committee on the Rules of Evidence, and Suggestions for Selective Revision of the Rules*, 60 Geo. Wash.L.Rev. 857, 861-62 & n.17 (1992). *See also* Minutes of the Advisory Committee on the Federal Rules of Criminal Procedure, April 23-24, 1992, at 13.

only through *amendment* of the FRE. A subcommittee of that Council, chaired by Solicitor General Starr, recommended "fifty specific *changes* to our *current* civil litigation system" which could be "implemented," *inter alia*, by "amendment to the rules of . . . evidence." *Proposed Civil Justice Reform Legislation*, 60 U. Cin. L. Rev. 977, 979 (1992) (emphasis added). Six of these changes related to the admissibility of expert testimony. *Id.* at 990.

The Starr subcommittee described the current state of evidence law, and its alleged defects, as follows:

> The Federal Rules of Evidence . . . eliminated many of the common law restrictions on the use of expert witnesses. . . .
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> . . . .
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> . . . Currently, "expert" witnesses are permitted to offer testimony even if their theories are unproven and are not corroborated by other experts. The Council's recommendations would allow testimony based on respected minority or majority theories while excluding fringe theories.

Id. at 999.

According to the subcommittee's report, the "Action *Required*" to achieve these changes included amendments to Rule 702 that would "require expert testimony to be based on 'widely accepted' theories." *Id.* at 999. "It is contemplated that this requirement may be satisfied by expert testimony that is accepted by at least a substantial minority of experts in the relevant field." *Id.* at 1050. Yet the Acting Solicitor General's brief filed in this case asks the Court to find in the present text of Rule 702 what the Starr subcommittee earlier acknowledged necessitated amendment of that Rule. *See, e.g.*, U.S. Br. 19-20.

There is a raging contemporary debate about the desirability of changing the FRE to increase the foundational requirements for admitting expert testimony. See, e.g., p. 7, note 11, *supra*. However, as this Court observed in the context of another controversial provision of the FRE: "Our task in deciding this case . . . is not to fashion the rule we deem desirable but to identify the rule that Congress fashioned." *Green v. Bock Laundry Machine Co.*, 490 U.S. 504, 508 (1989).

D. Rule 702 Does Not Contain a Foundational "Reliability" Threshold

Under the interpretation we have proffered, the FRE as presently constituted impose several important restrictions on expert scientific testimony that a judge may invoke to exclude "junk science." Rule 201(g) empowers a judge to refuse admission to testimony in disproof of a fact that is amenable to judicial notice, *i.e.*, that is "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Rule 201(b).[12] The availability of this power disposes of many of the extreme hypotheticals proffered in opposing briefs. Rule 702 restricts expert testimony to subjects on which the fact-finder needs expert assistance, and requires that the expert who is to testify be qualified. Rule 703 — the provision expressly addressed to the foundation for expert testimony (entitled "Bases of Opinion Testimony by Experts") — requires that the hearsay "facts or data" upon which the expert's opinion is predicated be "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Rule 403 empowers the trial judge to exclude expert testimony on a case-specific, *ad hoc* basis when the probative value of the proffered testimony is substantially outweighed by, *inter alia*, "the danger of unfair prejudice, confusion of the issues, or misleading the jury."

Additionally, even if testimony survives these "gateways" and is admissible, the judge may counter perceived "venal experts" by calling a court-appointed expert (Rule 706), and the opposing party may through cross-examination and the testimony of its own expert witnesses inform the jury of the extent of scientific disagreement with the witness' position. Further, the judge possesses the customary powers to grant judgment as a matter of law, either before or after the jury's verdict, if "there is no

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[12] *See* Advisory Committee's Note to Rule 201(g). In the instant case, Merrell never suggested that the court could take judicial notice of the safety of Bendectin, and the district court, which recognized that it is possible on the existing record that Bendectin causes limb defects (J.A. 236), plainly would have rejected the suggestion had it been made.

legally sufficient evidentiary basis for a reasonable jury to have found for [a] party" (Fed. R. Civ. P. 50(a)(1)), or to order a new trial if convinced that the verdict is manifestly against the weight of the evidence (Fed. R. Civ. P. 59).[13]

In our opening brief we laid out this framework of existing tools permitting judicial scrutiny of testimony by experts. Pet. Br. 35-37. Merrell and its *amici*, however, ask this Court to discover still additional "foundational" hurdles to the admissibility of expert testimony in Rule 702 (the section which, conspicuously, *precedes* the section entitled "Bases of Opinion Testimony by Experts"). These hurdles are claimed to flow from the term "knowledge" (or "scientific . . . knowledge") and the reference to experts testifying "thereto." Resp. Br. 13-14.

The precise content these proponents would inject into Rule 702 varies widely, from the "'accepted standards' foundational requirement" urged by Merrell (Resp. Br. 27) to a multitude of variations proposed by *amici*. The very breadth of the proposals showered on this Court suggests that these inventive "interpretations" have no root in the statute's language or legislative history: there is no anchor to guide or constrain the inventors' imaginations, because there is nothing in Rule 702 addressed to foundation. The dissonance between these proposals and the actual text of Rule 702 is evident from a comparison of Merrell's formulation with the text of Rule 702. Merrell argues (Resp. Br. 26):

> In summary . . . Rule 702 of the Federal Rules of Evidence requires a determination not only (1) that the resolution of a question warrants the use of expert testimony and (2) that a particular expert is qualified in his or her field, but also (3) that the testimony proffered by an expert rests on a foundation reflecting the generally accepted standards in that field for validating expert assertions.

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[13] Moreover, the plaintiff must establish all the factual predicates without which the expert's views would be irrelevant. In this case, for example, petitioners must show that the mothers ingested Bendectin during the brief, critical period of limb formation in the fetus. Pet. Br. 7 n.20; J.A. 192.

But only standards (1) and (2) of Merrell's formulation can be found in the text of Rule 702:

> [1] If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, [2] a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise. (Brackets added.)[14]

Merrell's attempt to graft a third standard onto Rule 702 is new in this Court. Below, Merrell's position was that the expert testimony in this case was inadmissible because of Rule 703.[15]

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[14] Similarly, the Advisory Committee's Note explaining Rule 702 contains only the first two of Merrell's proposed standards, and also quotes a passage from Mason Ladd, *Expert Testimony*, 5 Vand. L. Rev. 414, 418 (1952), describing only the first two standards. Pet. Br. 31 n.58.

Merrell suggests that, as the Advisory Committee's Note to Rule 702 cited Wigmore's treatise for the proposition that evidence could be excluded if "unhelpful," the drafters meant to empower judges to keep out opinions that are not "reliable." Merrell distorts the meaning by taking the citation out of context. In the section of the treatise cited by the drafters (7 Wigmore § 1918), Wigmore was using "unhelpful" to describe expert testimony that was not needed, either because the jury could resolve the issue without the benefit of expert advice or because the testimony would be duplicative of other expert testimony proffering the same opinion. The Advisory Committee's Note invoked this passage of Wigmore to explain the drafters' use of the phrase "assist the trier of fact" in Rule 702. See Pet. Br. 30-33.

[15] The lone reference to Rule 702 in Merrell's brief below was the following introductory passage describing "the nature of the analysis required to determine whether expert testimony is admissible" (Ct. Appeals Br. 17):

> First, under Rule 702 of the FRE, a court must determine whether the admission of expert testimony will assist the trier of fact. Second, under Rule 703, a court must inquire into whether the expert testimony is based upon data of a type reasonably relied on by the experts in the field in forming opinions.

Id. The remainder of the brief invoked only Rule 703 and the district court's discretionary power under Rule 403. *Id.* 33, 35, 37, 42-43.

The decisions of the courts below never cited Rule 702; rather, the courts said they were following other circuits that had applied *Rule 703* to bar testimony by certain experts called by plaintiffs in Bendectin cases. J.A. 229, 240 n.1.[16] In opposing rehearing below, Merrell repeatedly declared that the court had properly decided on the basis of Rule 703.[17] Finally, in its brief in opposition to certiorari in this Court, Merrell defended the decision below as consistent with Rules 703 and 403, without argument based on Rule 702.[18]

What accounts for Merrell's sudden discovery that the term "knowledge" in Rule 702 is the locus of the relevant foundational requirement?[19] Obviously, Merrell now realizes that the foundational requirement expressly prescribed in Rule 703 does *not* authorize exclusion of the testimony of petitioners' witnesses, because that testimony is predicated entirely upon facts and data "of a type reasonably relied upon by experts in a particular field [teratology] in forming opinions or inferences upon the subject [whether a toxin causes birth defects]." Pet. Br. 5, 34-37.[20]

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[16] Merrell tells this Court (Resp. Br. 12 n.6) that the Ninth Circuit's citation in the opinion below of its prior decision in *United States v. Solomon*, 753 F.2d 1522 (9th Cir. 1985), signals that the decision below was predicated on Rule 702. That misreads *Solomon*. As a glance at *Solomon* reflects, the page of *Solomon* cited in the opinion below (p. 1526) adopted *Frye* apparently as a free-standing common law rule for scientific evidence; the prior page (p. 1525) — *not* cited by the Ninth Circuit below — described Rule 702 in a separate passage as a threshold test for all expert testimony.

[17] Opposition to Petition for Rehearing, filed Feb. 18, 1992, at 1, 5, 12, 13, 17.

[18] See Respondent's Brief in Opposition, at 9, 11, 14-15, 17, 19.

[19] We use the term "discovery" advisedly: we are aware of no antecedents either in the case law or the commentaries for finding a foundational requirement in Rule 702's words "knowledge" and "thereto," and none is cited in the opposing briefs. The belatedness of this discovery, supposedly made simultaneously by Merrell and several of its *amici*, attests to its lack of merit.

[20] Some *amicus* briefs attempt to justify exclusion on the basis of Rule 703, but the attempt is meritless. The data upon which petitioners' experts rely is the same data upon which Merrell's experts rely. The dispute that divides the experts is not over the appropriate facts and data to consult, but rather over the conclusions to be drawn therefrom.

The efforts to transform "knowledge" in Rule 702 into a foundational requirement fly in the teeth of the statutory language and structure. Rule 703's very title — "Bases of Opinion Testimony by Experts" — announces that *it* is the provision prescribing the foundational requirements.[21]

Reading Rule 702 to permit testimony only if based upon relatively well-settled propositions of "knowledge" not only displaces the function of Rule 703; it is incompatible with Rule 702's language explicitly allowing experts to testify "in the form of an opinion." Merrell asserts that Rule 702 does not permit an expert to offer "beliefs" (Resp. Br. 14), but a check of any dictionary will confirm that this word is a synonym for "opinions."[22]

The only reading of Rule 702 consistent with its wording is that which we have proposed: Where expert testimony would assist the trier of fact in resolving a factual issue, a qualified expert may utilize his or her specialized knowledge to proffer an opinion as to the issue, so long as the opinion is predicated upon facts or data meeting the foundational requirements of *Rule 703*.[23]

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[21] "Foundation" and "basis" are synonyms. BURTON'S LEGAL THESAURUS 234 (1980) ("foundation"); WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 182 (1981) ("basis"); BLACK'S LAW DICTIONARY 151 (6th ed. 1990) ("basis").

[22] *See, e.g.*, definitions of "opinion" in: WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1582 (1981); BALLENTINE'S LAW DICTIONARY 893 (3d ed. 1969). *See also* definition of "opinion evidence" in BLACK'S LAW DICTIONARY 1093 (6th ed. 1990).

[23] Merrell argues that Rules 702 and 703 cannot mean what they plainly say because that would result in a lower threshold for admitting expert opinion testimony than the thresholds expressly provided in the FRE for the taking of judicial notice (Rule 201) and the admission of learned texts (Rule 803(18)). Resp. Br. 16. But the distinction is obvious: a high threshold for use of judicial notice or admission of learned texts is required because these methods of proof are not available for cross-examination, and cross-examination was the principal bulwark against poor science

III. THE INADEQUACY OF THE EFFORT TO BRUSH OFF FEDERALISM CONSIDERATIONS

No party or *amicus* challenges petitioners' contentions that under California law the expert testimony in this case would be admissible and sufficient to sustain a verdict in favor of petitioners. As this evidence would be admissible in the courts of at least 45 and perhaps all 50 States (see p. 2, *supra*), it is inescapable, and Merrell concedes (Resp. Br. 27 n.18), that adoption of an interpretation of Rule 702 that required exclusion of this evidence would change the outcomes of cases arising under the substantive tort law of the States.

Merrell and its *amici* nonetheless dismiss this consequence as unimportant for three reasons: (1) petitioners' interpretation of the FRE, requiring admission of the testimony, would likewise be outcome determinative in States whose courts would not admit the testimony; (2) *Erie* is inapplicable if Congress has enacted rules that bar admissibility of the evidence; and (3) in any event, judge-jury allocations involve the "fundamental character" of the federal courts and thus are exempt from *Erie* concerns. All of these rejoinders are flawed.

1. State law determines the substantive tort standards and defines the evidence sufficient to establish a claim. If a State has set the plaintiff's burden so high that this evidence would not satisfy the burden — imagine, for example, a State that ruled, as the courts below did, that causation must be proved by statistically significant epidemiological evidence — the evidence might not even be relevant, and in any event would be insufficient to sustain the plaintiff's burden of going forward and would justify summary judgment. It is only the *exclusion* of evidence that threatens a State's primacy over its tort law, for

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envisioned by the drafters of the FRE. See Pet. Br. 17, 39-40. On this basis, Dean McCormick had argued prior to the drafting of the FRE that general acceptance was an appropriate threshold for judicial notice, but not for the admission of expert testimony. Pet. Br. 17. Furthermore, Merrell offers no explanation why, if the drafters wanted similar thresholds with respect to expert testimony, similar words do not appear in Rules 702 and/or 703.

only exclusion disables state substantive law from operating upon the entire body of information that the State deems relevant.

2. It is, of course, true that *Erie* does not apply *when* Congress enacts a valid statute that preempts state substantive law. But Merrell's argument here overlooks the weight that is owing to federalism concerns in determining *whether* Congress has enacted such a statute.

The crux of the controversy here is a question that is properly controlled by state tort law: whether causation sufficient to justify a compensatory award can be found on the basis of animal and chemical data, in conjunction with epidemiological data that may fall short of demonstrating causation at a 95 percent significance level. The District of Columbia Court of Appeals has said that it can. Pet. Br. 42. We contend, and no one has disputed, that California courts would hold likewise. The courts below, however, construed the Federal Rules of Evidence to dictate the opposite answer. In doing so, they mistakenly deferred to scientists on an issue that is properly one of tort law.

"Determining the legal consequences that flow from this imperfect state of knowledge lies beyond the domain of science." Carnegie Commission Br. 22. And the choice as to what quantum of probabilistic causation evidence will suffice to legitimate a compensatory award in a products liability case requires a policy choice balancing, *inter alia*, the injured party's interest in compensation against the defendant's interest in not being held liable without adequate justification.

The courts below failed to appreciate that the question of whether causation "is likelier than not" is a different question from the one pursued by pure science. As evidence scholar Charles Nesson, one of Merrell's counsel, has written:

> The legal standard requires neither *absolute* certainty nor the exacting level of certainty that scientists employ for the demonstration of scientific propositions. There is a difference, then, between the testifying expert and the lab scientist. An imaginative scientist exploring the hypothesis that a given toxic agent causes cancer is very likely to suspend scientific judgment on the ultimate

> question of causation until more testing or study can be done to eliminate alternative hypotheses. A doctor or lawyer or judge, on the other hand, often does not have the luxury of postponing a decision. Often he must make a judgment once he reaches a reasonable working conclusion. Likewise, we ask juries to come to conclusions without insisting on or waiting for scientific demonstration. The legal standard of proof would seem to require only a rational basis for the expert's opinion — a standard far short of scientific demonstration.

Charles Nesson, *Agent Orange Meets the Blue Bus: Factfinding at the Frontier of Knowledge*, 66 B.U. L. Rev. 521, 529-30 (1986) (emphasis added).

The "lab scientist's" standard of proof — statistical significance — is heavily weighted *against* finding causation. Pet. Br. 9-10. In consequence, as Nesson explains, imposing that standard as the threshold for finding causation in toxic tort cases "*is tantamount to institutionalizing an objectively determinable probability greater than .5 for cases in which proof of causation involves a disputed supposition about the working of nature.*" *Id.* at 538-39 (emphasis added). This point has been made widely in the literature, by both legal scholars and scientists.[24]

Of course, a State might opt for a substantive rule of law withholding compensation in the absence of "statistically significant" evidence, despite the tilt in favor of producers that Nesson warns "insulates companies from the consequences of negligently exposing persons to toxins" and creates disincentives

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[24] *See, e.g.*, Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of* Agent Orange *and Bendectin Litigation*, 86 Nw. U. L. Rev. 643, 667-68, 682-94, 697 (1992); V. Brannigan, V. Bier, and C. Berg, *Risk, Statistical Inference, and the Law of Evidence: The Use of Epidemiological Data in Toxic Tort Cases*, 12 Risk Analysis 343 (1992); D.H. Kaye, *Is Proof of Statistical Significance Relevant?*, 61 Wash. L. Rev. 1333 (1986); Steve Gold, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion, and Statistical Evidence*, 96 Yale L.J. 376 (1986); Neil B. Cohen, *Confidence and Probability: Burdens of Persuasion in a World of Imperfect Knowledge*, 60 N.Y.U. L. Rev. 385, 413-14 (1985).

for taking appropriate care.[25] But as the Carnegie Commission's brief explains (at 24), whether to do so is a function of "the social policies underlying products liability law."[26]

Several of the *amici* supporting Merrell explicitly ask this Court to weigh and resolve that policy choice in arriving at its interpretation of the FRE. The brief filed by the Acting Solicitor General asks this Court to hold that expert testimony not buttressed by statistically significant epidemiological results is not admissible because it is "insufficient *as a matter of law* to support a finding that Bendectin caused the birth defects at issue in this case." U.S. Br. 14 (emphasis added). Three *amici* predicate their arguments for a statistical significance threshold for admissibility on the proposition that a reduction in the number of tort recoveries will assure the supply of products and services and strengthen the insurance mechanism.[27]

These are considerations that (if true) are appropriate for consideration by the governmental entity responsible for developing substantive tort policy, to be weighed together with the other interests (such as compensating injured persons and deterrence) that are relevant to that policy. But surely Congress did not purport to be making tort policy when it enacted the

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[25] Nesson, *supra*, 66 B.U. L. Rev. at 537.

[26] For like reasons, it is a question of tort law, rather than evidence law, whether a State will require evidence suggesting a doubling of incidence of injuries before finding causation in the case of individuals. *Cf.* Resp. Br. 40. There is a developing trend in favor of awarding proportionate recoveries on the basis of evidence of an increase in incidence, even if less than a doubling. The recent report of the American Law Institute, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY, Vol. II, 369-75 (1991), strongly endorses proportionate awards, concluding that they better serve both the deterrent and the compensation goals of tort law. *See also* STEVEN SHAVELL, ECONOMIC ANALYSIS OF ACCIDENT LAW 115-17 (1987). The seminal decisions adopting proportionate awards are *Herskovits v. Group Health*, 664 P.2d 474 (Wash. 1983), and *McKellips v. Saint Francis Hospital*, 741 P.2d 467 (Okla. 1987).

[27] AMA Br. 18-26; Pharmaceutical Manufacturers' Association Br. 12-18; American Insurance Association Br. 24-28.

FRE; it went out of its way to avoid doing so. Pet. Br. 41-42. The FRE cannot plausibly be construed to erect a burden of proof for tort causation in excess of the traditional "more probable than not" standard for a civil case, or to preclude the consideration of expert testimony on the ground that, "as a matter of law," animal studies, chemical studies, and epidemiological studies lacking *95 percent* confidence — which regulatory agencies act upon every day — are inadmissible to prove causation.[28]

3. The foregoing analysis cannot be escaped by simply labeling the issue here — as Merrell does in passing — as one of mere allocation of fact finding between judge and jury. See Resp. Br. 27 n.18 (citing *Byrd v. Blue Ridge Rural Elec. Corp., Inc.*, 356 U.S. 525 (1958)). The interpretation of the FRE sought by Merrell does not merely allocate the responsibility for "truth-determining." Washington Legal Foundation Br. 5. Rather, the question here — whether the testimony is sufficient to prove causation — is an issue respecting the nature of the burden of proof, which this Court unequivocally has determined to be "substantive." *Dick v. New York Life Ins. Co.*, 359 U.S. 437, 446 (1959).

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[28] Merrell and others argue that what regulators do is different, because regulators only need evidence of "risk" to act, while courts require a rigorous showing of "actual causation" before awarding tort damages. Resp. Br. 39-40. This is a false dichotomy. Banning products from the market imposes heavy social costs, just as awarding compensation does. In each case, the government does not want to take that step unless there is a sufficient showing of probability of "actual causation." Thus, in each case, government expects scientists to employ the methodologies most appropriate to making that assessment.

To be sure, the precise confidence level required of the probabilistic evidence before deciding to act may differ, depending upon the governmental action that is contemplated and the content of government policy, but that difference might cut either way. In some instances, government opts to allow products on the market, and relies on the tort system as a safety net, both to compensate those who are injured and to discover new information (through the continuous accumulation of information from individual cases) that may dictate the need for renewed regulatory interest. In these instances, government requires a *greater* showing of probability of causation before regulating than before compensating.

IV. THE PROPER DISPOSITION OF THIS CASE

Unless this Court affirms both holdings of the Ninth Circuit challenged here — that the FRE requires general acceptance as a threshold to the admissibility of expert testimony, and that (contrary to federal regulations and many *amici* scientists) "reanalysis" of epidemiological data is a "technique" subject to the *Frye* rule and is not generally accepted unless first published and peer reviewed — the normal course would be to reverse and remand for further proceedings. The briefs of Merrell and some *amici* raise two alternatives, however, that necessitate brief discussion.

1. Merrell and others ask this Court, if it rejects the Ninth Circuit's interpretation of the FRE, to determine in the first instance whether the evidence is admissible under the proper standard. We have no objection to that course. The testimony of petitioners' experts, from the ultimate conclusions stated in affidavits reprinted in the Joint Appendix to the hundreds of pages of testimony in which each expert carefully recounts the precise facts, data, methodology and reasoning upon which these conclusions are predicated,[29] measured against the pertinent tort law of California, demonstrates that the evidence here is admissible under any of the standards proffered in any of the briefs supporting Merrell (except those demanding prior publication and peer review as a precondition to admissibility). Indeed, as the Ninth Circuit's opinion reflects, the testimony would have been admissible even under its erroneous interpretation of the FRE, but for that Court's factual error respecting the functions of publication and peer review. *See* Pet. Br. 47-49; Chubin Br. *passim*.

2. The American Law Professors' brief broaches the option of this Court's dismissing this case to await the possible promulgation of a new rule by the recently appointed Advisory Committee on evidence, but then concludes that the Court should *not* dismiss. Law Profs. Br. 28-29. We agree, and briefly highlight certain factors that support the Court's deciding the issue now.

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[29] Tabs 12, 21, 26, 32, cited in Pet. Br. 3 n.4.